THE UNITED STATES DISTRICT COURT
DISTRICT OF UTAH

In re Myriad Genetics, Inc. Securities Litigation	**MEMORANDUM DECISION AND ORDER DENYING [51] DEFENDANTS' MOTION TO DISMISS AND GRANTING IN PART AND DENYING IN PART [59] MOTION TO STRIKE** Case No. 2:19-cv-00707-DBB-DBP District Judge David Barlow

Before the court is Defendants' Motion to Dismiss.[1] Defendants argue that Plaintiffs' Amended Class Action Complaint fails to state a claim upon which relief may be granted and must be dismissed under Rule 12(b)(6) of the Federal Rules of Civil Procedure. Also before the court is Plaintiffs' related Motion to Strike and Request for Judicial Notice.[2] Having reviewed the briefing, pleadings, exhibits, and relevant law, the court now rules as follows.

I. BACKGROUND[3]

As required at the motion to dismiss stage, the court treats all of Plaintiff's well-pleaded factual allegations as true. The court does not make any findings about the truth or falsity of Plaintiffs' claims.

Lead Plaintiff Los Angeles Fire and Police Pensions (Los Angeles) administers the defined benefit retirement plan for employees of the City of Los Angeles.[4] Los Angeles and other

[1] Motion to Dismiss, ECF No. 51.

[2] Motion to Strike and Request for Judicial Notice, ECF No. 59.

[3] Plaintiffs' Amended Complaint spans more than 140 pages and contains 338 individually numbered paragraphs. Primarily at issue in the instant motion to dismiss is whether the complaint sufficiently alleges misrepresentations and omissions actionable under federal securities laws. The court provides a truncated summary background here.

[4] Amended Complaint, ECF No. 34 at ¶ 37.

Plaintiffs acquired Myriad Genetics (Myriad) stock.[5] Principally based in Salt Lake City, Myriad is a molecular diagnostic company that develops and markets genetic lab tests screening for the presence of certain traits or diseases.[6] The individual Defendants are: Mark C. Capone, Myriad's former President and Chief Executive Officer; Bryan Riggsbee, Myriad's Chief Financial Officer during the class period and interim President and CEO; and Bryan M. Dechairo, Myriad's Executive Vice President of Clinical Development.[7]

Myriad's products include a pharmacogenomic test called "GeneSight" and genetic tests for hereditary cancer.[8] Pharmacogenomic testing attempts to combine pharmacology, the branch of medicine concerned with effects and modes of drugs, with genomics, the branch of biology concerned with the structure and function of genes.[9] Generally, the purpose is to understand how genes affect a person's responses to drugs. Myriad claimed that GeneSight could inform drug-prescribing decisions and significantly improve patient outcomes by providing doctors with information about how patients would metabolize specific drugs based on their genetic makeup. Most significantly, GeneSight included panels to test: (1) psychotropic drugs used to treat major depressive disorder; (2) analgesic drugs used to treat pain; and (3) drugs used to treat Attention-Deficit/Hyperactivity Disorder (ADHD).[10] Myriad claimed that GeneSight used a proprietary algorithm to make prescribing recommendations for specific drug therapies based on the

[5] *Id.*

[6] *Id.* at ¶ 43.

[7] *Id.* at ¶¶ 39, 40, 41, 42.

[8] *Id.* at ¶ 43.

[9] *Id.* at ¶ 44.

[10] *Id.*

patient's genetic makeup and presented those recommendations in an easy-to-understand format.[11]

Assurex, an Ohio company, originally developed GeneSight and initiated the GUIDED study, a clinical study designed to evaluate the GeneSight test.[12] After Myriad's acquisition of Assurex and GeneSight in 2016, revenue for the GeneSight product grew quickly, eventually overtaking the hereditary cancer test as Myriad's largest volume product.[13] The revenue of GeneSight was reported to be "a major driver of [Myriad stock's] valuation."[14]

On a February 7, 2017 investor call, Capone told Myriad investors that GeneSight's revenue was "rapidly approaching our current hereditary cancer revenue, showing the potential for this product to be transformative to our growth trajectory."[15] On an August 8, 2017 investor call, Capone said that GeneSight "would represent revenue of $500 million per year" equating to Myriad's Company-wide revenue for all of 2017 "if fully reimbursed."[16] Later that year, Myriad reported that GeneSight had achieved "a new [revenue] record at $28.8 million" and had achieved explosive growth of "54% year-over-year on an adjusted basis and 12% sequentially."[17] During the class period, Myriad repeatedly discussed the growth and extensive market potential for the GeneSight product.[18]

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[11] *Id.* at ¶ 45.

[12] *Id.* at ¶¶ 47, 48.

[13] *Id.* at ¶¶ 48, 49.

[14] *Id.* at ¶ 51 (excerpting a statement from a May 9, 2018 report from BTIG (a capital market company) analysts).

[15] *Id.* at ¶ 48.

[16] *Id.* at ¶ 49.

[17] *Id.*

[18] *See id.* at ¶¶ 48–50. The alleged class period is August 9, 2017 to February 6, 2020. *Id.* at 1.

Until mid-2017, Former Employee 2 (FE 2), worked as a Medical Science Liaison first at Assurex Health and then at Myriad. FE 2 helped develop the Company's communications about GeneSight but reported that the science did not support GeneSight's use of the ADHD and analgesic panels.[19] FE 2 also reported that he raised these data concerns with Defendant Dechairo before the class period.[20]

In its August 2017 Form 10-K filed with the U.S. Securities and Exchange Commission, Myriad stated that GeneSight was "clinically proven" to "enhance medication selection" for "ADHD," "chronic pain," and "depression," among other conditions.[21]

From May 2018 to April 2019, Former Employee 1 (FE 1) worked as a Medical Science Liaison at Myriad.[22] FE 1 stated that Myriad had "no data" supporting the efficacy of the ADHD and analgesic panels during the class period, and that Myriad's claim that it could match patients to specific ADHD and analgesic drugs based on the genes was "unsubstantiated" and "conjecture."[23] FE 1 further reported that, despite repeated calls to validate the effectiveness of GeneSight ADHD and analgesic panels, Myriad Neuroscience President Mark Veratti declined to perform the additional testing and analysis.[24] FE 1 reported that by late 2018, 30% to 40% of all GeneSight tests ordered were driven by demand for the ADHD panel.[25]

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[19] *Id.* at ¶ 62. "FE" represents an unnamed former employee.

[20] *Id.* at ¶ 64.

[21] *Id.* at ¶¶ 56, 57; ECF No. 52-3 at 7.

[22] ECF No. 34 at ¶ 65.

[23] *Id.*

[24] *Id.*

[25] *Id.* at ¶ 67.

The GUIDED study was critical to GeneSight's success.[26] With respect to the study, Defendant Capone told investors that it was "the most important milestone for reimbursement . . . for GeneSight."[27] Myriad described it as a "double-blind, multi-center, randomized controlled trial assessing the impact of the GeneSight Psychotropic test (GeneSight) on psychiatric treatment response in 1,200 patients with major depressive disorder (MDD)."[28] The study provided two study arms, a guided GeneSight therapy arm and a treatment as usual arm.[29] The GUIDED study protocol provided that the study's primary endpoint was "symptom improvement," defined as a change in the patient's score on the Hamilton Depression Scale 17 (HAMD-17), a commonly used scale involving 17 different factors to measure depression symptoms, after 8 weeks of treatment.[30] The study had 65 secondary endpoints and it required correction of the statistical significance threshold for multiple testing under certain circumstances.[31] The GUIDED study ultimately failed to achieve the primary study endpoint as there was no statistically significant difference in symptom improvement between the guided GeneSight arm and the treatment as usual arm.[32]

Reporting on the GUIDED study on November 2, 2017, Myriad highlighted two secondary endpoints: the remission rate and response rate.[33] Myriad stated in a press release:

> The study was designed to evaluate three key endpoints relative to HAMD-17 scores: remission (HAMD-17 score ≤7), response (HAMD-17

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[26] *See id.* at ¶¶ 51, 74, 75, 95, 96, 97, 164, 185, 213.

[27] *Id.* at ¶ 75.

[28] *Id.* at ¶ 77.

[29] *Id.* at ¶ 78.

[30] *Id.* at ¶ 80.

[31] *Id.* at ¶¶ 81, 90.

[32] *Id.* at ¶¶ 80–83.

[33] *Id.* at ¶¶ 85, 86.

> reduction >50%), and symptom reduction. Patients receiving the GeneSight test achieved a clinically meaningful and statistically significant improvement in both remission rates ($p<0.01$) and response rates ($p=0.01$) at eight weeks compared to the treatment-as-usual group. In addition, patients who received the GeneSight test had a greater reduction in HAMD-17 scores after eight weeks, compared to the treatment-as-usual group, with the difference approaching statistical significance ($p=0.1$). Lastly, the improvement in remission, response, and symptoms continued throughout the 24-week study period, demonstrating the durability of the benefit through that period.[34]

Dechairo stated in a press release about the study, "Improving remission and response rates are key treatment goals of clinicians because they directly improve patients' lives and reduce healthcare costs."[35] Dechairo continued, "These endpoints also align with payer goals, and we look forward to having those discussions in the coming months."[36] But Myriad did not adjust the threshold for significance of the reported remission and response results.[37] And a manuscript detailing the GUIDED study was rejected for publication in the American Journal of Psychiatry.[38] FE 1 reported that, among other things, the peer reviewers pointed out that GeneSight had failed to achieve the study's primary endpoint, and that Myriad's reliance on the results of two secondary endpoints was misplaced, since those results had not been adjusted for multiplicity.[39]

On October 31, 2018, the U.S. Food and Drug Administration (FDA) publicly issued a Safety Communication that "warn[ed] against the use of many genetic tests with unapproved

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[34] *Id.* at ¶ 86; *see* Exhibit 99.1 attached to Form 8-K, ECF No. 52-12 at 5.

[35] ECF No. 34 at ¶ 93.

[36] *Id.*

[37] *Id.* at ¶¶ 89, 90, 105–14.

[38] *Id.* at ¶¶ 117–19.

[39] *Id.* at ¶ 119.

claims to predict patient response to specific medications."[40] In a response on November 6, 2018, Capone stated that the FDA was

> well aware that there's a pretty significant difference between GeneSight, which is a combinatorial pharmacogenomic test that has clear clinical evidence demonstrating improved patient outcomes. That difference is pretty stark when you compare it to the single gene approach that one might see in the more recreational genomic testing.[41]

Capone further stated:

> And we believe that GeneSight is the only pharmacogenomic test supported by level 1 evidence, which demonstrates improved patient outcomes. As a reminder, GeneSight has completed 4 clinical studies, including the 1,200 patient prospective blinded and randomized guided study that was conducted consistent with the FDAs guidance on clinical trials for depression. The GUIDED study compared the GeneSight arm to an active drug arm and demonstrated a 50% improvement in symptoms and 30% improvement in response rates, both of which were highly statistically significant, and a 14% improvement in symptoms, which was approaching statistical significance.[42]

Later, Myriad stated that "the study design is in line with the recent FDA draft guidance for MDD trials."[43] Myriad continued to state that the GUIDED study distinguished itself and its GeneSight test from the tests of competitors.[44]

On August 1, 2019, Myriad announced that United Healthcare had decided to cover the GeneSight test.[45] The announcement boosted Myriad's stock price by 55%.[46] The same day, in pre-planned stock sales, Capone and Riggsbee sold 31% and 10% of their respective

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[40] *Id.* at ¶ 21; ECF No. 52-13.

[41] ECF No. 34 at ¶ 126.

[42] *Id.* at ¶ 284.

[43] *Id.* at ¶ 126; ECF No. 52-10 at 8.

[44] ECF No. 34 at ¶ 126.

[45] *Id.* at ¶¶ 137–39.

[46] *Id.* at ¶ 137.

personally-held Myriad stock.[47] Two weeks later, on August 13, 2019, Myriad held an earnings call after the close of the markets.[48] During the call, Myriad announced that it had discontinued GeneSight ADHD and analgesic panels in May 2019, acknowledging that these panels were not supported by adequate evidence and that some payors had refused to reimburse for administration of the panels.[49] Myriad disclosed that shortly after the panels were withdrawn, the reduced demand for GeneSight caused a 23% decline in GeneSight revenue.[50] Myriad's stock price dropped approximately 42% on August 14, 2019.[51]

On November 4, 2019, Myriad disclosed that it had overstated the revenue for a different set of panels—its breast and ovarian cancer tests—by $18 million.[52] In response, Myriad stock value dropped approximately 40%.[53] An earlier series of changes in billing codes preceded the revenue overstatement disclosure. In 2016, the Center for Medicare and Medicaid Services (CMS) merged two medical billing codes Myriad used to seek reimbursement for its breast and ovarian cancer panels.[54] In 2017, CMS added other billing codes for multi-gene screening in response to the proliferation of large-panel screening, testing for variations associated with different types of cancer.[55] Both of these code changes reduced, by about half, the reimbursement

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[47] *Id.* at ¶ 137.

[48] *Id.* at ¶ 175.

[49] *Id.*

[50] *Id.* at ¶ 60.

[51] *Id.* at ¶ 183.

[52] *Id.* at ¶ 141.

[53] *Id.* at ¶¶ 29, 193.

[54] *Id.* at ¶ 143. In *Association for Molecular Pathology v. Myriad Genetics, Inc.*, 569 U.S. 576 (2013), the Supreme Court rejected Myriad's claim to a patent over naturally-occurring genetic information in certain genes. As relevant here, the inability to patent the genetic discovery led to more competition in the hereditary cancer screening market, which "[put] negative pricing pressure" on Myriad's tests. *See id.* at ¶ 54.

[55] *Id.* at ¶ 144.

rate Myriad could expect for its hereditary cancer screens.[56] In 2019, the American Medical Association (AMA) formally deleted the two billing codes that CMS merged in 2016, and AMA replaced them with new codes pricing the procedures at approximately $1,100, or half of the cost of the merged code.[57] Despite the downward pressure on pricing for hereditary cancer tests, Myriad continued to assume the higher 2016 merged code rate and report on its books the higher expected revenue.[58] As of June 2019, however, Myriad had observed an increase in the number of denied claims and "short" payments for its hereditary cancer tests.[59] About five months later, Myriad made the revenue disclosure identified above.[60]

On February 6, 2020, Myriad announced that Defendant Capone would be resigning as Chief Executive Officer effectively immediately.[61] Myriad also disclosed that it was experiencing challenges obtaining reimbursement from UnitedHealthcare for its GeneSight tests, despite its coverage decision.[62] Consequently, tests under UnitedHealthcare contributed very little to Myriad's overall GeneSight sales and the company announced a significant revenue shortfall.[63] The announcements led to an approximately 28% decline in Myriad stock prices on February 6,

[56] *Id.* at ¶¶ 143, 144. The 2016 billing code was priced at $2,200 or 10% below what Myriad had been billing. *Id.* The two 2017 codes allowed billing at $1,400 combined. *Id.*

[57] *Id.* at ¶ 145.

[58] *Id.* at ¶ 145.

[59] *Id.* at ¶ 148.

[60] *See id.* at ¶ 141.

[61] *Id.* at ¶ 194.

[62] *Id.* at ¶ 196.

[63] *Id.*

2020.[64] On February 10, 2020, Dechairo allegedly was demoted from his position as an executive officer.[65]

II. MOTION TO STRIKE

As an initial matter, Lead Plaintiff requests that twelve exhibits attached to Defendants' Motion to Dismiss be stricken.[66] Lead Plaintiff also requests that the court take judicial notice of fourteen additional documents.[67]

In their motion to dismiss, Defendants challenge the sufficiency of Plaintiffs' Amended Complaint.[68] In support of their motion, Defendants attached thirty-six exhibits, comprised of more than a thousand pages, purported to be "incorporated by reference" in the Amended Complaint or "judicially noticeable."[69] "In evaluating a Rule 12(b)(6) motion to dismiss, courts may consider not only the complaint itself, but also attached exhibits and documents incorporated into the complaint by reference."[70] The purpose of a court's Rule 12(b)(6) motion review "is not to weigh potential evidence that the parties might present at trial, but to assess whether the plaintiff's complaint alone is legally sufficient to state a claim for which relief may be granted."[71] "Although the sufficiency of a complaint must rest on its contents alone, there are

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[64] *Id.* at ¶ 198.

[65] ECF No. 57 at 56; ECF No. 34 at ¶¶ 217–19.

[66] ECF No. 59 at 1–2. Plaintiffs challenge Defendants' exhibits 1, 6, 16, 20, 21, 24, 25, 26, 27, 29, 32, and 33 attached to the Declaration of John F. Sylvia offered in support of the motion to dismiss. Declaration of John F. Sylvia, ECF No. 52.

[67] ECF No. 59; ECF No. 58.

[68] *See generally* ECF No. 51.

[69] ECF No. 51 at 2 n.1 (stating that "[a]ll exhibits attached to the Sylvia Declaration are either incorporated by reference in the [Amended Class Action Complaint] or judicially noticeable"); *see generally* ECF No. 52.

[70] *Smith v. United States*, 561 F.3d 1090, 1098 (10th Cir. 2009) (citations and internal quotation marks omitted).

[71] *Jacobsen v. Deseret Book Co.*, 287 F.3d 936, 941 (10th Cir. 2002) (quoting *Sutton v. Utah State Sch. for Deaf & Blind*, 173 F.3d 1226, 1236 (10th Cir. 1999)).

exceptions to this restriction on what the court can consider."[72] However, these exceptions are "quite limited," and include: "(1) documents that the complaint incorporates by reference; (2) documents referred to in the complaint if the documents are central to the plaintiff's claim and the parties do not dispute the documents' authenticity; and (3) matters of which a court may take judicial notice."[73] In a securities case, the court "may consider, in addition to the complaint, documents incorporated by reference into the complaint, public documents filed with the SEC, and documents the plaintiffs relied upon in bringing suit."[74] "When there are allegations that certain disclosures were not made in publicly available documents, [the court] may look to those documents to see whether such disclosures were in fact made."[75]

Defendants attached to their motion, among other things, financial analyst reports, a patient brochure, a third-party position statement on pharmacogenomic testing, reporting forms from a third-party drug company, a letter from third parties to federal administrative agencies, and journal articles.[76] The exhibits Plaintiffs challenge are not incorporated by reference in the Amended Complaint, nor are they referred to in the Amended Complaint and central to plaintiffs' claims.[77] At bottom, Plaintiffs claim alleged misrepresentations by Myriad and the individual Defendants over a period of time kept stock prices artificially high and obscured the risks to

[72] *Wasatch Equal. v. Alta Ski Lifts Co.*, 820 F.3d 381, 386 (10th Cir. 2016) (brackets, citation, and internal quotation marks omitted).

[73] *Id.* at 386 (citation and internal quotation marks omitted).

[74] *Slater v. A.G. Edwards & Sons, Inc.*, 719 F.3d 1190, 1196 (10th Cir. 2013) (citing *ATSI Commc'ns, Inc. v. Shaar Fund, Ltd.*, 493 F.3d 87, 98 (2d Cir. 2007)).

[75] *Id.* (citing *Roth v. Jennings*, 489 F.3d 499, 509 (2d Cir. 2007)).

[76] *See generally* ECF No. 52.

[77] *See Wasatch Equal.*, 820 F.3d at 386.

stockholders. Plaintiffs refer to none of the challenged exhibits in the complaint.[78] In sum, the challenged exhibits are not referred to in the Amended Complaint and therefore not subject to consideration under the *Jacobsen* exception.[79] Nevertheless, Defendants contend that the documents should be considered because they fit within the categories of documents courts sometimes consider in deciding motions to dismiss.[80] That they may be of the same type of documents considered by some district courts is insufficient to pull these documents within the limited exception authorizing consideration of material beyond the four corners of the complaint. For the same reasons, the court declines to take judicial notice of the fourteen documents Plaintiffs put forward in their motion to strike.[81]

III. LEGAL STANDARD

To survive a motion to dismiss under Rule 12(b)(6), a complaint must contain "sufficient factual matter, accepted as true, to 'state a claim to relief that is plausible on its face.'"[82] Dismissal is required when the complaint, standing alone, is insufficient to state a claim upon

[78] Defendants' Exhibits 1, 24, and 27 attached to the motion to dismiss are purported to be August 1, 2019, November 2, 2017, and May 8, 2018 Barclays reports, respectively. The Amended Complaint refers to Barclays reports, but not these.

Defendants' Exhibit 6 is a purported Assurex GeneSight marketing brochure. Although the Amended Complaint generally refers to Myriad's marketing, it does not refer to this document.

Defendants' Exhibit 16 is a purported United Healthcare medical policy update bulletin. Defendants' Exhibit 20 is purported to be a statement by the Association for Molecular Pathology. Defendants' Exhibit 21 is purported to be a letter to the FDA from mental health advocacy organizations. Defendants' Exhibits 25 and 26 are purported to be a press release from Sage Therapeutics, Inc. Defendants' Exhibits 29, 32, and 33 are purported to be 2017 journal articles. These articles are not referred to in the Amended Complaint.

[79] *See Jacobsen*, 287 F.3d at 941.

[80] *See* Opposition to Motion to Strike, ECF No. 68 at 6.

[81] Plaintiffs' requests for judicial notice includes an excerpt from the GUIDED study Statistical Analysis Plan, several journal and news articles, and an FDA clinical trials webpage, among other things.

[82] *Ashcroft v. Iqbal*, 556 U.S. 662, 678 (2009) (quoting *Bell Atl. Corp. v. Twombly*, 550 U.S. 544, 570 (2007)).

which relief may be granted.[83] Generally, to be facially plausible, each claim must be supported by well-pleaded facts allowing the court to "draw the reasonable inference that the defendant is liable for the misconduct alleged."[84] A claim is deficient and subject to dismissal if a plaintiff offers in support only "labels and conclusions," "a formulaic recitation of the elements," or "naked assertions devoid of further factual enhancement."[85] Reviewing a motion to dismiss, the court construes the complaint in favor of the plaintiff.[86]

Unlike other civil claims, complaints alleging securities fraud claims are subject to a more stringent pleading standard.[87] Section 10(b) of the Private Securities Litigation Reform Act (PSLRA), "makes it unlawful 'to use or employ, in connection with the purchase or sale of any security . . . any manipulative or deceptive device or contrivance in contravention of such rules and regulations as the SEC may prescribe as necessary or appropriate in the public interest or for the protection of investors."[88] Generally, to state a claim under Section 10(b), a plaintiff must allege:

> (1) the defendant made an untrue or misleading statement of material fact or failed to state a material fact necessary to make statements not misleading; (2) the statement complained of was made in connection with the purchase or sale of securities; (3) the defendant acted with scienter, that is, with intent to defraud or recklessness; (4) the plaintiff relied on the

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[83] *See Sutton v. Utah State Sch. for Deaf & Blind*, 173 F.3d 1226, 1236 (10th Cir. 1999) ("The court's function on a Rule 12(b)(6) motion is not to weigh potential evidence that the parties might present at trial, but to assess whether the plaintiff's complaint alone is legally sufficient to state a claim for which relief may be granted.").

[84] *Iqbal*, 556 U.S. at 678.

[85] *Id.* (citations, brackets, and internal quotation marks omitted).

[86] *Ash Creek Min. Co. v. Lujan*, 969 F.2d 868, 870 (10th Cir. 1992).

[87] *Weinstein v. McClendon*, 757 F.3d 1110, 1112 (10th Cir. 2014) (observing that the Private Securities Litigation Reform Act "mandates a more stringent pleading standard for securities fraud actions in general, and for scienter allegations in particular" (quoting *City of Philadelphia v. Fleming Companies, Inc.*, 264 F.3d 1245, 1258 (10th Cir. 2001)).

[88] *Adams v. Kinder-Morgan, Inc.*, 340 F.3d 1083, 1095 (10th Cir. 2003) (brackets omitted) (quoting 15 U.S.C. § 78j(b)), *as amended on denial of reh'g* (Aug. 29, 2003).

> misleading statements; and (5) the plaintiff suffered damages as a result of his reliance.[89]

The complaint must "specify each statement alleged to have been misleading, the reason or reasons why the statement is misleading, and, if an allegation regarding the statement or omission is made on information and belief, the complaint shall state with particularity all facts on which that belief is formed."[90] The scienter element of a securities fraud claim under the PSLRA also must be pleaded with particularity.[91] Further, "in determining whether the pleaded facts give rise to a 'strong' inference of scienter, the court must take into account plausible opposing inferences."[92] Together, these elements require plaintiffs to "bear[] a heavy burden at the pleading stage."[93]

IV. ANALYSIS

A. Plaintiffs Have Adequately Pleaded a Section 10(b) Claim Under the Exchange Act.

In their motion to dismiss, Defendants argue that Plaintiffs failed to plead the first and third elements of a Section 10(b) claim. Specifically, they contend that the Amended Complaint inadequately pleads that Defendants made misleading statements of fact (or omissions) and that

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[89] *Id.* (citing *Grossman v. Novell, Inc.*, 120 F.3d 1112, 1118 (10th Cir. 1997)).

[90] 15 U.S.C. § 78u-4(b)(1).

[91] *Id.* § 78u-4(b)(2); *see City of Philadelphia*, 264 F.3d at 1258 ("The term 'scienter' has been defined by the Supreme Court of the United States as 'a mental state embracing intent to deceive, manipulate, or defraud.'" (quoting *Ernst & Ernst v. Hochfelder*, 425 U.S. 185, 193 n.12 (1976)); *Adams*, 340 F.3d at 1095–96 (noting that "the PSLRA heightened the standard for pleading the scienter element of a securities fraud claim," superseding the general pleading requirement of Rule 9(b) of the Federal Rules of Civil Procedure); *cf.* Fed. R. Civ. P. 9(b) ("In alleging fraud or mistake, a party must state with particularity the circumstances constituting fraud or mistake. Malice, intent, knowledge, and other conditions of a person's mind may be alleged generally.").

[92] *Tellabs, Inc. v. Makor Issues & Rights, Ltd.*, 551 U.S. 308, 323 (2007).

[93] *See In re Level 3 Commc'ns, Inc. Sec. Litig.*, 667 F.3d 1331, 1333 (10th Cir. 2012).

Defendants acted with the requisite scienter.[94] Accordingly, the court limits its discussion to these two elements and addresses each in turn.

1. Allegations of Untrue or Misleading Statements

Plaintiffs' allegations about false or misleading statements may be grouped into four different categories: (1) statements about the efficacy of GeneSight's ADHD and analgesic panels; (2) statements about the GUIDED trial; (3) statements that omitted the withdrawal of the ADHD and analgesic panels and FDA's concerns about GeneSight; and (4) misleading statements about the hereditary cancer test revenue, including improper revenue statements in SEC filings.

a. Statements About the Efficacy of GeneSight's ADHD and Analgesic Panels

Myriad claimed that GeneSight's ADHD and analgesic panels were clinically proven to be "highly effective and improved clinical outcomes for patients whose doctors prescribed drugs recommended by the test."[95] Plaintiffs allege that "[i]n truth, as Defendants were well-aware, there was no meaningful evidence supporting GeneSight's claimed ability to predict patient response to particular ADHD or pain relief drugs."[96]

For example, Myriad is alleged to have made the following statements about GeneSight's ADHD and analgesic panels.

- On unspecified dates, but alleged to be "throughout the Class Period," Myriad stated on its website:

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[94] *See Adams*, 340 F.3d at 1095 (citing *Grossman*, 120 F.3d at 1118).

[95] ECF No. 34 at ¶ 56.

[96] *Id.* at ¶ 58.

> If you or your child have Attention-Deficit / Hyperactivity Disorder, this test can help quickly and accurately determine which drugs will work best with your (or your child's) genes;
>
> The GeneSight ADHD genetic test can reduce [the anxiety of taking ADHD drugs] by helping doctors to identify and avoid ADHD medications more likely to cause side effects based on your genetics; and
>
> For those experiencing acute or chronic pain, this test analyzes how your genes affect your body's response to FDA-approved opioids, NSAIDs and muscle relaxants to accurately determine which medications are optimal.[97]

- On August 9, 2017, Myriad filed with the SEC Form 10-K reporting the quarter and year ending on June 30, 2017, signed by Capone and Riggsbee, which stated:

> In the neuroscience market, our GeneSight test meets a significant unmet clinical need and is the leading product for psychotropic drug selection. It is used by healthcare providers to help patients who are affected by neuropsychiatric conditions including depression, anxiety, ADHD, bipolar disorder, schizophrenia, post-traumatic stress disorder (PTSD) and other behavioral health conditions, as well as chronic pain. The test is clinically proven to enhance medication selection, helping healthcare providers get their patients on the right medication faster.[98]

- On August 24, 2018, Myriad filed with the SEC Form 10-K reporting the quarter and year ending on June 30, 2018, signed by Capone and Riggsbee, which contained the same language as provided in the 2017 10-K.[99]

- On August 13, 2019, Riggsbee stated in a Myriad earnings call:

> in May, we made the decision to discontinue our analgesic and ADHD products because . . . the level of clinical evidence did not meet the same high standard set by the GeneSight psychotropic test in the GUIDED study. In addition, a few payers expressed similar views, and we wanted to

[97] *Id.* at ¶¶ 57, 224.

[98] *Id.* at ¶¶ 56, 221.

[99] *Id.* at ¶ 222.

> eliminate any potential hurdles to commercial payer coverage for GeneSight psychotropic.[100]

Plaintiffs allege these statements concerning the efficacy of the GeneSight ADHD and analgesic panels were misleading because there never was any meaningful evidence supporting GeneSight's claimed ability to predict patient response to particular ADHD or pain relief drugs.[101]

Plaintiffs allege that Defendants knew that the data available to Myriad prior to and during the Class Period failed to demonstrate a clinically meaningful relationship between the genes tested as part of the panels and patients' response to medication.[102] Plaintiffs specifically allege that two former employees brought the lack of evidence to the attention of senior management. "FE 1, a Medical Science Liaison at Myriad from May of 2018 to April of 2019 . . . helped develop the Company's communications about GeneSight" and stated that "the Company had 'no data' supporting the efficacy of the ADHD and analgesic panels during the Class Period, and that Myriad's claim that it could match patients to specific ADHD and analgesic drugs based on the genes was 'unsubstantiated' and 'conjecture.'"[103]

According to FE 1, the "issue was raised repeatedly with Myriad executives throughout his tenure."[104] "At a Company off-site meeting in July 2018, FE 1 and other Medical Affairs personnel met with Myriad Neuroscience President Mark Verratti and 'heated[ly]' repeated long-standing concerns that the Company needed to validate the effectiveness of the ADHD and

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[100] *Id.* at ¶¶ 59, 175.

[101] *Id.* at ¶ 58.

[102] *Id.* at ¶¶ 61-62, 65; *see id.* at ¶¶ 175, 223, 225, 227.

[103] *Id.* at ¶ 65.

[104] *Id.*

analgesic panels . . . ."[105] "FE 1 stated that Verratti acknowledged that Myriad had not validated GeneSight's ADHD and analgesic panels."[106] FE 1 also stated that "Medical Affairs personnel continued to raise issues concerning the absence of empirical support for the ADHD and analgesic panels with Mike Jablonski, Vice President of Medical Affairs at Myriad Neuroscience."[107] "Jablonski told FE 1 and his colleagues that he continued to relate their concerns to Verratti, but that Verratti remained unwilling to commence any testing or analysis to validate the panels."[108]

FE 2, "a Medical Science Liaison at Assurex Health and then at Myriad until mid-2017" stated that "it was well known within Myriad, including among Dechairo and other senior personnel, that the science did not support GeneSight's use of the ADHD and analgesic panels."[109] "Instead, according to FE 2, the data available to Myriad, which included non-public internal data collected from GeneSight patients, failed to demonstrate a clinically meaningful relationship between the genes tested as part of the ADHD and analgesic panels and patients' response to medications."[110] FE 2 further claimed that "he, along with colleagues in Medical Affairs and other Company employees, raised the lack of evidentiary support for the ADHD and analgesic panels directly with Defendant Dechairo on numerous occasions prior to the start of the Class Period, including at routine Company offsite meetings."[111] One of these meetings occurred

[105] *Id*.

[106] *Id*.

[107] *Id.* at ¶ 66.

[108] *Id*.

[109] *Id.* at ¶ 62.

[110] *Id*.

[111] *Id*. at ¶ 64.

during early 2017 in Park City, Utah, at which FE 2 says that he "described to Dechairo analyses the Company should perform to obtain necessary clarity on the efficacy of GeneSight's panels, including ADHD and analgesic."[112] "To FE 2's astonishment, Dechairo declined to consider these proposals, stating that the risk of a negative result would harm Myriad's ability to market GeneSight."[113]

Defendants argue that all "public mentions of GeneSight . . . plainly were referencing Myriad's proprietary GeneSight Pyschotropic test, the primary GeneSight test, and the clinical evidence supporting it."[114] But this is not at all clear from the above-quoted statements, and the court will not apply Myriad's interpretation of the statements to grant a motion to dismiss. Myriad further contends that its "clinically proven" statements are not misleading because it in fact had clinical data supporting its claim, and that its later withdrawal of the ADHD and analgesic products was not an admission of lack of supporting evidence.[115] Again, these interpretative arguments are not ones that will support a motion to dismiss.

Assuming, as the court must at this stage, that Plaintiffs' factual allegations are true, a lack of efficacy evidence may render misleading statements like the "test is clinically proven to enhance medication selection," the test can "accurately determine which medications are optimal," and "this test can help quickly and accurately determine which drugs will work best with your (or your child's) genes."[116] Statements that a scientific test has been proven to do something or that it will do something accurately when it has not, can be false or misleading, and

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[112] *Id.*

[113] *Id*.

[114] ECF No. 51 at 32.

[115] ECF No. 67 at 23–24.

[116] *See* ECF No. 34 at ¶¶ 56, 57, 221, 222.

by their nature would be material.[117] There is more than "a substantial likelihood" that the fact "would have been viewed by the reasonable investor as having significantly altered the 'total mix' of information made available."[118]

b. Statements About the GUIDED Clinical Study

Plaintiffs allege that Defendants made multiple kinds of misleading statements about the GUIDED study. First, Plaintiffs allege that Defendants repeatedly talked about the study as if it were designed around three endpoints,[119] when in fact GUIDED had one primary endpoint, which did not achieve statistical significance, and 65 secondary endpoints, two of which Myriad chose to emphasize.[120] Accordingly, it was misleading to treat the study as a success by downplaying the failure to achieve the primary endpoint and instead elevating the significance of two secondary endpoints.

For example, Plaintiffs allege that Myriad made these and other statements:

- On November 2, 2017, Myriad issued a press release announcing the results of the GUIDED study (the GUIDED Press Release), stating:

> The study was designed to evaluate three key endpoints relative to HAMD-17 scores: remission (HAMD-17 score ≤7), response (HAMD-17 reduction >50%), and symptom reduction. Patients receiving the GeneSight test achieved a clinically meaningful and statistically significant improvement in both remission rates ($p<0.01$) and response rates ($p=0.01$) at eight weeks compared to the treatment-as-usual group. In

[117] *See, e.g.*, *In re PTC Therapeutics, Inc. Sec. Litig.*, 2017 WL 3705801, at *14 (D.N.J. Aug. 28, 2017) (noting that defendant's statements were misleading where it told investors that it had proven that its drug was effective at treating a type of muscular dystrophy knowing it failed to meet FDA approval standards); *In re Medimmune, Inc. Sec. Litig.*, 873 F. Supp. 953, 967 (D. Md. 1995) (observing that defendant's statement was misleading where it went "beyond a bona fide claim that the test data are 'valid' or the drug 'efficacious'" and when an FDA review questioned the product's efficacy).

[118] *TSC Indus., Inc. v. Northway, Inc.*, 426 U.S. 438, 449 (1976).

[119] *See* ECF No. 34 at ¶ 229.

[120] *Id.*

addition, patients who received the GeneSight test had a greater reduction in HAMD-17 scores after eight weeks, compared to the treatment-as-usual group, with the difference approaching statistical significance (p=0.1). Lastly, the improvement in remission, response, and symptoms continued throughout the 24-week study period, demonstrating the durability of the benefit through that period.[121]

- On November 7, 2017, Capone stated the following in a Myriad earnings call:

  The primary goal was to assess the HAMD-17 scores at 4 and 8 weeks compared to baseline and to calculate 3 endpoints: percent of patients in remission; percent of patients that are responders; and the percent symptom reduction . . . . We believe the data from this study clearly demonstrates the clinical utility of the GeneSight test. We saw an improvement in depressive symptoms for the entire cohort, which was approaching statistical significance. More importantly, in the 2 most critical endpoints for physicians and payers, response and remission, we achieved a high degree of statistical significance.

  * * *

  After the 12-week endpoint, the 8-week endpoint was the primary endpoint for the evaluation of those 3 remission, response and symptom reduction.[122]

- On January 9, 2018, at the JP Morgan Healthcare Conference, Capone stated:

  The endpoint was based on HAMD-17 scores, which is a 17-item questionnaire that's administered to patients and certified by central raters. And there were 3 calculations based on that singular endpoint. Those being response, remission and symptom improvements.[123]

- On May 8, 2018, in a Myriad earnings call, Capone or Dechairo stated:[124]

  I would like to begin the discussion with GeneSight results starting with the 3 clinical outcomes of remission, response and symptom improvement over the 8-week blinded period of the study. Importantly, the GeneSight-guided arm performed better in all 3 areas, showing a highly statistically

[121] *Id.* at ¶ 228.

[122] *Id.* at ¶ 232.

[123] *Id.* at ¶ 236.

[124] The Amended Complaint duplicates the first paragraph here from the above alleged statement of Capone. *Compare id.* ¶ 243, *with id.* ¶ 244.

> significant improvement in remission and response rates and an improvement in symptoms that was trending towards statistical significance.[125]

Defendants contend that the statements are not actionable because they were true, the study's Protocol was publicly available, and because use of a word like "key" denotes a non-actionable opinion.[126] None of these arguments are sufficient to support a motion to dismiss on the facts of this case. The court will not find, as a matter of law, that these statements are "true" or that the Protocol's alleged public availability in an unspecified time and manner forecloses the possibility of any claim. The defense argument that one or more of the words were mere opinions also has no impact at this stage and on this record.

If Plaintiffs' allegations are true that GUIDED had a single primary endpoint and that endpoint was not successful, but Myriad described GUIDED's primary and secondary endpoints as if they were equivalents (e.g. "three key endpoints") or implied that the primary endpoint had been achieved (e.g., "the GeneSight-guided arm performed better in all 3 areas"), these and other statements like them could be found misleading, depending on the context.[127]

Based on the Amended Complaint's allegations, the statements also present "a substantial likelihood" that the fact "would have been viewed by the reasonable investor as having significantly altered the 'total mix' of information made available."[128] Given the importance

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[125] *Id.* at ¶ 244. Plaintiffs allege that other similar statements were also misleading, including those found at ¶¶ 247, 275.

[126] ECF No. 51 at 23–24.

[127] *Cf. Kleinman v. Elan Corp., plc*, 706 F.3d 145, 149 (2d Cir. 2013) (concluding that defendant's statement was not misleading where it stated its study "did not attain statistical significance on the primary efficacy endpoints in the overall study population, post-hoc analyses did show statistically significant and clinically meaningful benefits in important subgroups" (brackets omitted)); *see also In re Medimmune*, 873 F. Supp. at 967 (finding a statement misleading as to efficacy of a product where defendant stated "the results of treatment with Respivir were highly statistically significant along all of the efficacy parameters built into the Phase III study" (brackets omitted)).

[128] *TSC Indus.*, 426 U.S. at 449.

which Myriad ascribed to the GUIDED trial, the well-pleaded facts of the Amended Complaint suggest that Myriad's alleged repeated treatment of secondary endpoints as if they were of the same importance as the primary endpoint may have been viewed by the reasonable investor as altering the "total mix" of information.

Second, Plaintiffs allege that Myriad's promotion of the results of two secondary endpoints was misleading because FDA guidance and standard clinical study practice suggests that a study like GUIDED must demonstrate a treatment effect on the primary endpoint before a secondary endpoint may be analyzed.[129] In other words, Plaintiffs contend that because GUIDED's primary endpoint was not statistically significant, Myriad should not have been touting the statistical significance of any secondary endpoints at all.

As noted above, Myriad made numerous statements promoting the GUIDED study's results on response and remission.[130] Defendants contend that the FDA guidance cited by Plaintiffs is inapplicable because it applies to drugs and medical devices, not genetic tests, and further argue that secondary endpoints may be analyzed even when the primary endpoint is not met.[131] At this stage of the litigation, the court cannot resolve the competing factual allegations made by the parties. If it is true that applicable FDA guidance or good clinical trial practice prohibit analyzing secondary endpoints when the primary endpoint is not met in a study like GUIDED, then Defendants' numerous statements touting two of GUIDED's secondary endpoints

[129] ECF No. 34 at ¶ 200 (stating that FDA guidance "makes clear that 'positive results on the secondary endpoints can be interpreted only if there is first a demonstration of a treatment effect on the primary endpoint family'" (brackets and emphasis omitted)); *see id.* at ¶¶ 13, 81, 88, 173, 229, 231, 233, 235, 237, 239, 242, 246, 248, 250, 252, 254, 256, 262, 266, 268, 270, 272, 276, 278, 283, 287, 289, 291, 293, 295.

[130] Other examples are found at Amended Complaint ¶¶ 240, 245, 247, 251.

[131] ECF No. 51 at 21.

may be found materially misleading by altering "the 'total mix' of information made available."[132]

Third, Plaintiffs allege that the GUIDED study did not actually show statistical significance of the remission and response rate secondary endpoints because the GUIDED study protocol itself and FDA guidance required an adjustment Myriad failed to make.[133] The allegedly required but unmade adjustment in the base level of statistical significance was supposed to have been made to address a statistical issue called multiplicity.[134] Plaintiffs allege that former employees understood this problem and that, if the required adjustments were made, the results Myriad had promoted would not be statistically significant.[135]

Plaintiffs cite numerous statements by Myriad regarding statistically significant results from the GUIDED trial. For example:

- On November 16, 2017, Myriad offered a slide presentation to investors at the Jefferies Healthcare Conference stating the "top-line" results from the GUIDED study, including the following chart.[136]

Study Endpoint	**What it Means**	**Study Result**	**Importance to Clinicians and Payers**
Remission hardest to achieve	Patient no longer depressed	Highly statistically significant ($p<0.01$)	Very important
Response difficult to achieve	Patient feels a lot better	Highly statistically significant ($p<0.01$)	Very important
Symptom Improvement most likely to achieve	Patient feels somewhat better	Approaching statistical significance ($p=0.1$)	Meaningful

[132] *TSC Indus.*, 426 U.S. at 449.

[133] ECF No. 34 at ¶¶ 90, 237, 239, 242, 246, 248.

[134] *Id.*

[135] *Id.* at ¶¶ 110, 200.

[136] *Id.* at ¶ 234.

- On January 9, 2018, at the JP Morgan Healthcare Conference, Capone stated:

> The results of this study exceeded our expectation. They were outstanding. GeneSight showed highly statistically significant results in the endpoints that matter most. In fact, the most important endpoint is remission . . . . And GeneSight was highly statistically significant when compared to treatment as usual.
>
> GeneSight also was highly statistically significant at the response endpoint. . . . Also equally important is remission, response and symptoms improvements were durable.[137]

- On May 8, 2018, in response to an analyst question at the Deutsche Bank investor conference, Capone stated:

> Obviously, the data was exceptional. We're very pleased with it on many fronts. I think the most important thing we were able to demonstrate is significant improvements in remission and response, which are the endpoints that matter most to clinicians, to patients and to payers, and statistically significant results there.[138]

If, as plaintiffs allege, a relevant multiplicity adjustment was required but not made, then Myriad's numerous statements about the response and remission endpoints being statistically significant obviously could be materially misleading or false. If the results were not, in fact, statistically significant, there would be more than "a substantial likelihood" that the fact "would have been viewed by the reasonable investor as having significantly altered the 'total mix' of information made available."[139] Defendants contend that no multiplicity adjustments were required for GUIDED, arguing that GUIDED's Protocol did not require it and also contending that the SAP supersedes the Protocol and does not call for a multiplicity adjustment.[140] The

[137] *Id.* at ¶ 236.

[138] *Id.* at ¶ 241; *see also id.* at ¶¶ 245, 247, 251.

[139] *TSC Indus.*, 426 U.S. at 449.

[140] ECF No. 51 at 23.

Protocol itself contains the multiplicity correction language cited in the Amended Complaint, but it is present only in a subsection on phenotype analyses that does not clearly appear to apply to the remission and response endpoints.[141] Nevertheless, Plaintiffs have adequately alleged that the FDA guidance required the adjustment and that Myriad knew it was required.[142] The Amended Complaint contains sufficient well-pleaded facts on this point, and the Court will not resolve factual disputes on a motion to dismiss.

Fourth, Plaintiffs allege that Capone falsely stated on a November 2018 earnings call that Myriad had "voluntarily withdrawn" the GUIDED manuscript from publication review at the American Journal of Psychiatry "solely based upon the desire to protect our intellectual property" because the journal had requested a copy of the GeneSight algorithm.[143] Plaintiffs allege that the truth was that the American Journal of Psychiatry had twice rejected the manuscript because the primary endpoint had not been reached, reliance on the response and remission endpoints was misplaced, and for failure to adjust for multiplicity."[144]

Defendants argue in their Motion to Dismiss that Plaintiffs' claim is insufficiently supported because it comes from an anonymous former employee and no information is provided as to how he would have known what happened with the GUIDED manuscript submission.[145]

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[141] GUIDED Study Protocol, ECF No 52-9 at 43 (stating that "[t]o account for multiple testing, the Sidak correction will be employed . . . ."). The multiplicity correction appears to be required only in phenotype analyses. *Id.*

[142] ECF No. 34 at ¶ 89; *see id.* at ¶ 82 (FDA guidance states "It is recommended that the list of secondary endpoints be short, because the chance of demonstrating an effect on any secondary endpoint after appropriate correction for multiplicity becomes increasingly small as the number of endpoints increases."); *id.* at ¶ 110 ("FE 1 confirmed that the GUIDED protocol codified the requirement that the p-values for the results on the study's non-primary endpoints be adjusted for multiplicity and that, if the adjustment were made as required, *none* of the results were actually statistically significant").

[143] *Id.* at ¶¶ 123, 257.

[144] *Id.* at ¶¶ 119, 120, 123.

[145] ECF No. 51 at 27–28.

The Tenth Circuit has made it clear that "[d]efendants in securities fraud lawsuits do not require, for example, the name of the employee who provided plaintiffs with facts . . . so long as the facts alleged in the plaintiffs' complaint are detailed enough to support a reasonable belief that the defendant's statement identified by the plaintiffs were false or misleading."[146]

That standard is met here. If the facts are as alleged—that Myriad announced that its GUIDED manuscript had been withdrawn, rather than rejected, and that the reason for the withdrawal was solely due to an attempt to protect its intellectual property, rather than the journal's rejection of Myriad's principal claims about GUIDED—then the Myriad statement would be misleading or false. If this were known, there is "a substantial likelihood" that the fact "would have been viewed by the reasonable investor as having significantly altered the 'total mix' of information made available,"[147] at least on the facts Plaintiffs have alleged.

Plaintiffs also allege that Myriad falsely claimed that GUIDED "was conducted consistent with the FDA's Guidance"[148] and that "the study design is in line with the recent FDA draft guidance for MDD trials."[149] Plaintiffs contend that this was "flatly untrue."[150] But Plaintiffs do not then explain how it was "flatly untrue," simply summarizing and quoting parts of another case in their brief instead. To the extent that Plaintiffs intend a reference to their claims of false statistical significance, they have been addressed earlier in this opinion. To the extent that they intend some other argument, Plaintiffs offer no further explanation of how the statement was false or how it altered the total mix of available information.

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[146] *Adams*, 340 F.3d at 1102.

[147] *TSC Indus.*, 426 U.S. at 449.

[148] ECF No. 34 at ¶¶ 284, 286.

[149] *Id.* at ¶ 126.

[150] ECF No. 57 at 34.

Finally, Plaintiffs cite a Myriad statement that FDA was "well aware" that "GeneSight . . . has clear clinical evidence demonstrating improved patient outcomes."[151] This statement, and others like it, appear below:

- On Myriad's November 6, 2018 earnings call, Capone stated that the FDA was "well aware that there's a pretty significant difference between GeneSight, which is a combinatorial pharmacogenomic test that has ***clear clinical evidence*** demonstrating improved patient outcomes. That difference is pretty stark when you compare it to the single gene approach that one might see in the more recreational genomic testing."[152]

- "As many of you are aware the FDA issued a notice for pharmacogenomic testing last week cautioning providers and patients about tests with claims that are not clinically validated. We strongly agree with this position as unlike GeneSight most companies have not published clinical outcomes data supporting their tests. And we believe that GeneSight is the only pharmacogenomic test supported by level 1 evidence, which demonstrates improved patient outcomes. As a reminder, GeneSight has completed 4 clinical studies, including the 1,200 patient prospective blinded and randomized guided study that ***was conducted consistent with the FDAs guidance on clinical trials for depression***."[153]

- On Myriad's January 4, 2019 investor call, Capone specifically referenced a conversation he had with the FDA Director responsible for the division regulating medical devices on the same day the Safety Communication was issued, and stated "***we're in a very different space*** [from competing tests] . . . . So I know ***there is a very clear distinction in the line, and I think that distinction remains***."[154]

According to Plaintiffs, these statements were false because "they portrayed Myriad as somehow outside the scope of the FDA's scrutiny of pharmacogenomic testing and failed to disclose that GeneSight lacked evidence sufficient to support the test . . . ."[155] Plaintiffs continue on by realleging their claims about the data needing a multiplicity adjustment and the

[151] ECF No. 34 at ¶¶ 126–28.

[152] *Id.* at ¶ 126.

[153] *Id.* at ¶ 284.

[154] *Id.* at ¶ 126.

[155] *Id.* at ¶ 289.

insignificance of secondary endpoints.[156] Plaintiffs also make an assertion about the propriety of post-hoc analyses.[157]

These allegations do not meet the standard for a materially misleading or false statement. The quotes Plaintiffs offer do not appear to suggest that Myriad was "outside the scope of FDA's scrutiny." Allegations about the GUIDED results and multiplicity are addressed earlier in this opinion; these statements do not create additional potential for liability. Finally, Capone's November 2018 opinion that FDA was aware of the differences between GeneSight and its competitors does not appear to be materially false based on the allegations of the Amended Complaint.

c. Post-May 2019 Statements Omitting the FDA's Concerns About GeneSight and the Withdrawal of the ADHD and Analgesic Panels

Plaintiffs allege that Myriad's post-May 2019 statements about GeneSight that omitted references to FDA concerns about the product or that the ADHD and analgesic panels had been withdrawn were misleading.[158] The statements allegedly were misleading because they failed to disclose that FDA "was planning to issue the Company a Warning Letter on the grounds that Myriad's claims regarding GeneSight were unsupported."[159] And as a result of the threatened Warning Letter, Myriad withdrew the ADHD and analgesic panels, but did not state that they had withdrawn the panels until August 13, 2019.

The only post-May 2019 statement Plaintiffs cite on this point in their Opposition is Myriad's August 1, 2019 announcement that UnitedHealthcare had decided to cover the

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[156] *Id.*

[157] *Id.*

[158] ECF No. 57 at 38–40.

[159] *Id.* at 38.

GeneSight test.[160] Plaintiffs do not quote from that announcement or attach it to their Amended Complaint, but simply indicate that it occurred.[161]

For an omission to be potentially actionable, the defendant must have "failed to state a material fact necessary to make statements not misleading."[162] Specifically, the PLSRA provides that one avenue of liability is where defendant "omitted to state a material fact necessary in order to make the statements made, in light of the circumstances in which they were made, not misleading."[163] The Tenth Circuit has further found that "[a] duty to disclose arises only where both the statement made is material, and the omitted fact is material to the statement in that it alters the meaning of the statement."[164]

Plaintiffs do not plead sufficient facts regarding the August 1, 2019 statement about which they complain. The court has no basis to determine whether the FDA communications or the withdrawal of the ADHD and analgesic panels were material to that statement and needed to be included to prevent the announcement from being misleading.

d. Defendants' Statements and Omissions Concerning Hereditary Cancer Test Pricing

Plaintiffs also allege that Myriad made false statements about its hereditary cancer screening test pricing and resulting revenue. Plaintiffs assert that relevant test code changes in 2016, 2017, and 2019 resulted in a declining price that Myriad could actually charge for its cancer tests, but that Myriad booked revenue and told investors that the expected pricing and

[160] *Id.* at 38–40 (citing ECF No. 34 at ¶¶ 129–39).

[161] ECF No. 34 at ¶¶ 25, 137–38.

[162] *Adams*, 340 F.3d at 1095.

[163] *Id*. (quoting 15 U.S.C. § 78u-4(b)(1)).

[164] *McDonald v. Kinder-Morgan, Inc.*, 287 F.3d 992, 998 (10th Cir. 2002) (brackets, citation, and internal quotation marks omitted).

revenue would be far greater than it actually was.[165] Plaintiffs allege that Generally Accepted Accounting Principles or GAAP required Myriad to make changes in its revenue accrual model to take into account the likelihood of declining revenue and to disclose the uncertainty of the revenue in its financial statements, but Myriad did neither.[166] On November 4, 2019, Myriad disclosed that it had overstated the revenue for the cancer tests by $18 million.[167] In response, Myriad's stock dropped approximately 40%.[168]

Some of the statements Plaintiffs claim were false or misleading include:

- On February 5, 2019, Capone stated, "We delivered strong hereditary cancer results this quarter as year-over-year pricing headwinds abated . . . ."[169]
- On May 7, 2019, in its Form 8-K, Myriad stated that the hereditary cancer test "revenue growth reached four percent, the highest in the last five fiscal years" and asserted that the Company had "[a]chieved [its] . . . sixth consecutive quarter with stable hereditary cancer pricing."[170]
- On September 10, 2019, at the Morgan Stanley Healthcare Conference, analysts asked Capone whether he could discuss his guidance for hereditary cancer revenue in fiscal 2020, and he stated that "[t]his year we guided to relatively flat hereditary cancer revenues. And in that, we are anticipating modest volume growth being offset

[165] ECF No. 34 at ¶¶ 141–48.

[166] *Id.* at ¶¶ 147, 150–52 (citing specific GAAP standards allegedly violated).

[167] *Id.* at ¶ 141.

[168] *Id.* at ¶ 29.

[169] *Id.* at ¶ 303.

[170] *Id*.

> by modest price reduction. So that's the guidance we've provided for fiscal year [2020]."[171]

Plaintiffs allege that statements like these, which included phrases like "pricing headwinds abated," "stable hereditary cancer pricing" and "modest price reduction," were false and misleading because it "hid from investors Myriad's difficulties with hereditary cancer test reimbursement,"[172] which purportedly had been ongoing for years.[173] Plaintiffs also allege that Myriad's SEC filings stating revenue were false or misleading because they allegedly did not comply with GAAP.[174]

Defendants argue that the statements are not actionable as a matter of law because they are vague and constitute fraud by hindsight.[175] If it is true that Myriad was telling investors that its cancer test pricing was "stable" when it knew it was not or was booking revenue in SEC filings which it knew was not in compliance with GAAP, then the foregoing statements would be false or misleading.[176] Further, if Plaintiffs are correct that the subsequent restatement reduced revenue by $18 million[177] and resulted in a Myriad stock drop of approximately 40%, then there

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[171] *Id.*

[172] *Id.*

[173] *Id.* at ¶ 143–47.

[174] *Id.* at ¶ 298 (Myriad filed SEC Form 10-Q in May 2019 reporting hereditary cancer test revenue of $117.6 million for the three months ended on March 31, 2019 and stating that "[t]he accompanying condensed consolidated financial statements have been prepared . . . in accordance with U.S. generally accepted accounting principles ('GAAP') for interim financial information . . . ."); *id.* at ¶ 299 (Myriad filed SEC Form 10-K in August 2019, reporting hereditary cancer revenue for the fiscal year ended June 30, 2019 of $479.7 million stating that "[t]he accompanying consolidated financial statements have been prepared . . . in accordance with U.S. generally accepted accounting principles ('GAAP') for financial information . . . .").

[175] ECF No. 57 at 35–36.

[176] Of course, if the alleged GAAP violations are not supported by fraudulent intent, they are not actionable. *Dronsejko v. Thornton*, 632 F.3d 658, 669 (10th Cir. 2011).

[177] ECF No. 34 at ¶ 300.

is "a substantial likelihood" that the fact "would have been viewed by the reasonable investor as having significantly altered the 'total mix' of information made available."[178]

Considering the Amended Complaint in its entirety, as well as the documents incorporated by reference, the court concludes that Plaintiffs have met the heightened pleading standard applicable to alleged false, misleading, or omitted fact statements, as described above.[179] That is, Plaintiffs' Amended Complaint clearly and specifically identifies multiple statements of Defendants "alleged to have been misleading," and Plaintiffs offered "the reason or reasons why the statement is misleading."[180] Accordingly, this element is pleaded sufficiently.

2. Plaintiffs Adequately Pleaded Scienter.

To state a claim for securities fraud, Plaintiffs must plead scienter.[181] The PSLRA requires that the complaint, "with respect to each act or omission alleged to violate this chapter, state with particularity facts giving rise to a strong inference that the defendant acted with the required state of mind."[182] In this context, scienter consists of "a mental state embracing intent to deceive,

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[178] *TSC Indus.*, 426 U.S. at 449.

[179] *See Tellabs*, 551 U.S. at 322 (holding that courts "must consider the complaint in its entirety, as well as other sources courts ordinarily examine when ruling on Rule 12(b)(6) motions to dismiss, in particular, documents incorporated into the complaint by reference, and matters of which a court may take judicial notice"); *Adams*, 340 F.3d at 1095 (observing that "the PSLRA increased the burden on a plaintiff's pleading of the first element of a securities fraud action: the allegation that the defendant made a false or misleading statement, or failed to state a material fact necessary to make statements made not misleading").

[180] 15 U.S.C. § 78u-4(b)(1).

[181] *See Tellabs*, 551 U.S. at 319 (observing that plaintiffs asserting Section 10(b) claims "must prove that the defendant acted with scienter, a mental state embracing intent to deceive, manipulate, or defraud" (citation and internal quotation marks omitted)).

[182] 15 U.S.C. § 78u-4(b)(2)(A). "[I]n determining whether the pleaded facts give rise to a 'strong' inference of scienter, the court must take into account plausible opposing inferences." *Tellabs*, 551 U.S. at 323. That is, it considers any "plausible, nonculpable explanations for the defendant's conduct," and "inferences favoring the plaintiff." *Id.* at 324.

manipulate, or defraud, or recklessness."[183] That is, in addition to acting with the "primary purpose of misleading shareholders[,] scienter also exists when a defendant acted with a reckless disregard of a substantial likelihood of misleading investors."[184] "A complaint will survive . . . only if a reasonable person would deem the inference of scienter cogent and at least as compelling as any opposing inference one could draw from the facts alleged."[185]

Plaintiffs contend that the following allegations adequately plead scienter: (1) Myriad scientists told senior management that the ADHD and analgesic panels lacked evidence;[186] (2) Myriad failed to follow the GUIDED clinical trial protocol and FDA guidance; [187] (3) a panel of experts twice warned Myriad that its statements on GeneSight's efficacy were unsupported;[188] (4) Myriad failed to account for known decreases in payor reimbursements;[189] (5) Capone and Riggsbee sold millions of dollars of stock prior to announcing bad news on the GeneSight panels;[190] (6) the alleged misstatements were the subject of intense regulatory scrutiny;[191] and (7) Capone abruptly resigns and Dechairo was demoted.[192] The court considers the allegations as a whole.

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[183] *Anderson v. Spirit Aerosystems Holdings, Inc.*, 827 F.3d 1229, 1236–37 (10th Cir. 2016) (internal quotation marks omitted) (quoting *Adams*, 340 F.3d at 1105); *see Tellabs*, 551 U.S. at 319, 319 n.3 (observing that plaintiffs asserting Section 10(b) claims "must prove that the defendant acted with scienter, a mental state embracing intent to deceive, manipulate, or defraud" and noting every Court of Appeals that had considered the question also included recklessness (citation and internal quotation marks omitted)).

[184] *Nakkhumpun v. Taylor*, 782 F.3d 1142, 1150 (10th Cir. 2015).

[185] *Tellabs*, 551 U.S. at 324.

[186] ECF No. 57 at 43–47.

[187] *Id.* at 47–49.

[188] *Id.* at 49–50.

[189] *Id.* at 50–52.

[190] *Id.* at 52–54.

[191] *Id.* at 56.

[192] *Id.* at 56–57.

a. Myriad Scientists' Concern about the Absence of Evidence Supporting GeneSight ADHD and Analgesic Panels

Plaintiffs allege that prior to and during the class period "it was well known within Myriad, including among Dechairo and other senior personnel, that the science did not support GeneSight's use of the ADHD and analgesic panels."[193] As discussed above, Plaintiffs rely heavily on statements from two former employees, identified as FE 1 and FE 2. FE 1 was a Medical Science Liaison at Myriad from May 2018 to April 2019.[194] FE 2 also was a Medical Science Liaison, first at Assurex Health and then at Myriad (after it acquired Assurex) until mid-2017.[195] Both FE 1 and FE 2 helped developed Myriad's communications about GeneSight.[196]

According to FE 2, Myriad's data on these panels "failed to demonstrate a clinically meaningful relationship between the genes tested as part of the ADHD and analgesic panels and patients' response to medications."[197] Indeed, FE 2 asserted that the "overwhelming consensus" within Myriad's Medical Affairs department was that the data did not support the use of these panels.[198] FE 2 and his colleagues "raised the lack of evidentiary support for the ADHD and analgesic panels directly with Defendant Dechairo on numerous occasions prior to the start of the Class Period."[199] One such meeting occurred in early 2017 in Park City, Utah.[200] At this

[193] ECF No. 34 at ¶¶ 61–62.

[194] *Id.* at ¶ 65.

[195] *Id*. at ¶ 62.

[196] *Id* at ¶¶ 62–65.

[197] *Id.* at ¶ 62.

[198] *Id.* at ¶ 63.

[199] *Id.* at ¶ 64.

[200] *Id.*

particular meeting, FE 2 "described to Dechairo analyses the Company should perform to obtain necessary clarity on the efficacy of GeneSight's panels, including ADHD and analgesic."[201] Dechairo refused to consider the proposal for additional testing "stating that the risk of a negative result would harm Myriad's ability to market GeneSight."[202]

FE 1 confirmed that Myriad "had 'no data' supporting the efficacy of the ADHD and analgesic panels," and that Myriad's claim that these panels could match certain drugs to patients' genes was "'unsubstantiated' and 'conjecture.'"[203] FE 1 stated that the issue "was raised with Myriad executives throughout his tenure."[204] He described a "heated" meeting with Myriad Neuroscience President Mark Veratti in July 2018 in which scientists again expressed "long-standing" concerns about the lack of evidence supporting the efficacy of the GeneSight ADHD and analgesic panels.[205] According to FE 1, Verratti acknowledged the lack of validation testing for GeneSight's ADHD and analgesic panels and understood that Medical Affairs "did not want to be selling a product without support," but that Myriad was not inclined to perform the testing or analysis.[206] FE 1 continued to express concerns to Mike Jablonski, Vice President of Medical Affairs at Myriad Neuroscience, who indicated he related the concerns to Veratti, to no avail.[207]

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[201] *Id.*

[202] *Id.*

[203] *Id.* at ¶ 65.

[204] *Id.*

[205] *Id.*

[206] *Id.*

[207] *Id.* at ¶ 66.

Later in 2019, when Myriad decided to withdraw the ADHD and analgesic panels, Myriad allegedly prepared a script for Myriad personnel to use with doctors who were reluctant to stop using the tests.[208] The script advised Myriad personnel to ask the doctor "Do you want to prescribe a test to a patient that has little or no data?"[209]

Defendants argue that these allegations do not plead scienter because: (1) the "allegations are stale" since they precede Dechairo's statements in August 2017 and 2018; (2) Myriad's alleged script in June 2019 instructing employees to tell doctors not to use them anymore because they were supported by "little or no data" does not show scienter on the earlier dates when the allegedly misleading statements were made; and (3) the unnamed employees should be accorded "little weight" because their statements are vague.[210]

First, regarding Defendants' staleness argument, the Amended Complaint alleges Myriad made misleading or false claims about the ADHD and analgesic panels on its website "throughout the Class Period."[211] The Amended Complaint further alleges that additional misleading or false claims about those panels were made in SEC filings in August 2017 and August 2018.[212] Defendants are correct that there is only one specific allegation that Dechairo himself (as opposed to Veratti, Joblonki, or "Myriad executives") was told that the data were lacking occurred in "early 2017." While some event between "early 2017" and August 2017 could have occurred that may have affected Dechairo's scienter, Defendants do not identify any.

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[208] *Id*.

[209] *Id*. at ¶ 69.

[210] ECF No. 67 at 7–10.

[211] ECF No. 34 at ¶¶ 57, 224.

[212] *Id.* at ¶¶ 221, 222, 223.

And to decide whether Plaintiffs have stated a claim against Myriad, the court considers the allegations about what the other named Myriad executives allegedly were told as well.[213]

Second, Defendants contend that June 2019 statements about "little or no data" supporting the ADHD and analgesic panels are meaningless because they came long after the allegedly false efficacy statements. This argument does not address the FE 1 and FE 2 statements that Myriad never had sufficient data and that executives had been advised of same, so it is not more compelling than the view supporting scienter.

Finally, Defendants contend that the court should give the confidential witnesses' allegations little weight: "Because the substance of these allegations is so vague, and because their provenance is so dubious, their impact is negligible."[214] The court agrees that the fact that these witnesses are not named decreases their credibility and usefulness.[215] However, unnamed witnesses are permitted in pleadings,[216] and the Amended Complaint provides sufficient information about these witnesses and their allegations for pleadings purposes. Plaintiffs provided the witnesses' titles, the span of their employment with Myriad, and allegations of specific incidents in which they participated, including an early 2017 Park City, Utah meeting

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[213] In a securities fraud case, "[t]he inquiry is whether all of the facts alleged, taken collectively, give rise to a strong inference of scienter, not whether any individual allegation, scrutinized in isolation, meets [the standard for Rule 12(b)(6) dismissal]." *Tellabs*, 551 U.S. at 310.

[214] ECF No. 67 at 9.

[215] *See Adams*, 340 F.3d at 1102 (observing that "personal or documentary sources for the key allegations" in a complaint need not be disclosed, but "by disclosing such sources plaintiffs can significantly strengthen their pleading"). Indeed, where the fact sources re not identified, the allegations "will usually have to be particularly detailed, numerous, plausible, or objectively verifiable by the defendant before they will support a reasonable belief that the defendant's statements were false or misleading." *Hampton v. root9B Techs., Inc.*, 897 F.3d 1291, 1299 (10th Cir. 2018) (quotation marks omitted) (quoting *Adams*, 340 F.3d at 1103).

[216] *Id.* ("Defendants in securities fraud lawsuits do not require, for example, the name of the employee who provided plaintiffs with facts, or the title of the internal report relied upon by the plaintiffs, so long as the facts alleged in the plaintiffs' complaint are detailed enough to support a reasonable belief that the defendant's statements identified by the plaintiffs were false or misleading.").

and a July 2018 meeting, as well as the names of various Myriad executives. Unlike cases where such statements have proved insufficient at the pleadings stage, Plaintiffs do not "simply state[] that an unidentified employee working for the defendant believed that a certain corporate profit statement was misleading"[217] or "report only conclusory assertions about the defendants' scienter."[218]

b. Myriad Failed to Follow the GUIDED Clinical Trial Protocol and FDA Guidance

As discussed earlier, Plaintiffs allege that the GUIDED protocol and FDA guidance required a statistical adjustment for GUIDED secondary endpoints to correct for multiplicity, but that Myriad did not perform the required adjustment.[219] If the required adjustment had been made, none of the results would have been statistically significant.[220] Plaintiffs also allege that FDA guidance stated that no secondary endpoint analysis should be performed at all when the primary endpoint is not met, but that Myriad did so anyway.[221]

Defendants argue that there is no inference of scienter because the GUIDED protocol does not require a multiplicity adjustment for the remission and response endpoints, and that GUIDED was not subject to the FDA guidance cited by Plaintiffs.[222] As noted earlier, the GUIDED protocol contains the multiplicity correction language cited in the Amended Complaint, but it does not clearly appear to apply to the remission and response endpoints.[223]

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[217] ECF No. 51 at 40 (quoting *Adams*, 340 F.3d at 1102).

[218] *Zucco Partners, LLC v. Digimarc Corp.*, 552 F.3d 981, 998 (9th Cir. 2009).

[219] ECF No. 34 at ¶ 200.

[220] *Id.* at ¶¶ 105, 106, 110, 200.

[221] *Id.* at ¶ 200.

[222] ECF No. 67 at 10–14.

[223] *See supra* note 141.

However, Plaintiffs have alleged that Myriad employees knew a multiplicity adjustment was required.[224] Regarding the FDA guidance, no facts have been pleaded that it was binding, but Myriad affirmatively stated that GUIDED was conducted in accordance with FDA guidance.[225]

This is sufficient to support an inference of scienter at the pleadings stage. If, as Plaintiffs allege, Myriad understood that a multiplicity correction was required, failed to perform the adjustment, and knew that performing the adjustment would result in a lack of statistical significance, it would be at least reckless to proceed with touting the remission and response results. The same holds true for the allegation that no secondary endpoint analysis should have been performed in light of the failed primary endpoint.[226] If, as alleged, it was clearly improper to use the secondary endpoints under these circumstances, then doing so anyway would support a scienter inference.

c. Experts Warned Myriad about GeneSight Efficacy Statements

Plaintiffs allege that a panel of peer reviewers from the American Journal of Psychiatry twice warned Myriad privately that the GUIDED study data did not support the efficacy of GeneSight.[227] In seeking to publish the GUIDED study results, Myriad submitted a manuscript to

[224] ECF No. 34 at ¶ 90 (FDA guidance states, "It is recommended that the list of secondary endpoints be short, because the chance of demonstrating an effect on any secondary endpoint after appropriate correction for multiplicity becomes increasingly small as the number of endpoints increases"); *id.* at ¶ 110 ("FE 1 confirmed that the GUIDED protocol codified the requirement that the p-values for the results on the study's non-primary endpoints be adjusted for multiplicity and that, if the adjustment were made as required, *none* of the results were actually statistically significant.").

[225] *Id.* at ¶ 284 ("GeneSight has completed 4 clinical studies, including the 1,200 patient prospective blinded and randomized guided study that was conducted consistent with the FDAs guidance on clinical trials for depression."); *id.* at ¶ 126 ("[T]he study design is in line with the recent FDA draft guidance for MDD trials.").

[226] *See* ECF No. 34 at ¶¶ 12, 13, 81, 88, 94, 110, 119, 166, 173, 200, 201, 229.

[227] ECF No. 34 at ¶ 201. The information about Myriad's alleged interactions with the American Journal of Psychiatry is relayed through FE 1.

the American Journal of Psychiatry.[228] In late summer 2018, the journal allegedly declined to publish the manuscript because, among other things, the peer review panel observed that the study had failed to achieve its primary endpoint and because the highlighted results on two of the secondary endpoints had not been adjusted for multiplicity and would not have been statistically significant after adjustment.[229] Myriad submitted a response and the journal again declined publication citing the lack of scientific validity of the GUIDED study manuscript.[230]

Defendants do not address the scienter inference on this point. If Plaintiffs' allegations are correct, the American Journal of Psychiatry's reviewers' statements about the failure of the primary endpoint and lack of statistical significance support an inference of scienter involving Myriad's statements about GUIDED's efficacy post-rejection. Relatedly, Capone's allegedly false statement in a November 2018 earnings call that Myriad had "voluntarily withdrawn" the GUIDED manuscript from publication review at the American Journal of Psychiatry "solely based upon the desire to protect our intellectual property"[231] strengthens the scienter inference. To be clear, the fact that GUIDED was not published by AJP does not, alone, support scienter. But the combination of the alleged warnings from the reviewers and Capone's subsequent statement about what happened to the submission would.

d. Known Declines in Payor Reimbursements

[228] *Id.* at ¶¶ 18, 117, 201, 252.

[229] *Id.* at ¶ 201; *see id.* at ¶ 18 (alleging that "Myriad hid from investors how, when it attempted to submit the GUIDED study publication to the prestigious American Journal of Psychiatry for publication, the journal privately rejected it twice because Myriad's draft relied on GUIDED's secondary endpoints, which were not statistically significant").

[230] *Id.* at ¶ 201.

[231] *Id.* at ¶¶ 123, 257.

Plaintiffs allege that Myriad's hereditary cancer tests were under pricing pressure because of billing code changes from 2016 to 2019.[232] Despite the downward pressure on pricing, Myriad allegedly continued to report on its books the higher expected revenue[233] and did not comply with GAAP by failing to identify this contingency.[234] Myriad also made multiple statements in 2019 regarding its cancer panel pricing that did not reflect falling prices and revenue, including phrases like "pricing headwinds abated," "stable hereditary cancer pricing" and "modest price reduction."[235] By June 2019, Myriad had observed an increase in the number of denied claims and "short" payments for its hereditary cancer tests.[236] On November 4, 2019, Myriad disclosed that it had overstated the revenue for its breast and ovarian cancer tests by $18 million.[237]

Defendants argue that the statements are not actionable as a matter of law because they constitute fraud by hindsight and because GAAP violations alone do not show scienter.[238] Defendants also note that health care billing is complex and generally contend that there are no facts alleged that suggest that Defendants knew the statements were false when they were made.[239]

Defendants are correct that a GAAP violation alone is not enough and that allegations that "defendant should have anticipated future events and made certain disclosures earlier,"

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[232] *Id.* at ¶¶ 143–45.

[233] *Id.* at ¶ 145.

[234] *Id.* at ¶¶ 147, 150–52, 298, 299.

[235] *Id.* at ¶ 303.

[236] *Id.* at ¶ 148.

[237] *Id.* at ¶ 141.

[238] ECF No. 67 at 4.

[239] *Id*. at 5-6.

standing alone, are insufficient to state a claim for securities fraud.[240] Instead, plaintiffs must provide "an explanation as to why the disputed statement was untrue or misleading *when made*."[241]

Plaintiffs have done that adequately here and have pleaded additional relevant facts. The Amended Complaint alleges that no later than June 2019, Myriad had evidence that its cancer panel pricing, which was undermined by the January 2019 AMA billing code cancellation, was not holding up.[242] Despite that, around the same time, Myriad was talking about "stable hereditary cancer pricing."[243] Later, in September 2019, Myriad stated that there were "modest price declines" involving the panels.[244] Less than two months later, the company made its earnings restatement.[245] Plaintiffs further allege that Myriad made SEC filings where it knew it was required to identify the pricing contingency, but failed to do so.[246] Finally, the court must consider the August 1 stock sale discussed below, which provides further support for the scienter inference about the timing of the cancer panels pricing statements and earnings restatement. Assuming that these and the other allegations regarding scienter are true, this is enough to support the scienter inference of recklessness at the pleadings stage.

e. Capone and Riggsbee Stock Sales

[240] *City of Philadelphia*, 264 F.3d at 1260 (10th Cir. 2001).

[241] *Id.* (citing *Grossman*, 120 F.3d at 1124 (10th Cir. 1997)).

[242] *Id.* at ¶ 148.

[243] *Id*.

[244] *Id.*

[245] *Id.* at ¶ 141.

[246] *See* ECF No. 57 at 51.

Plaintiffs allege that Capone and Riggsbee sold substantial amounts of Myriad stock in a pre-planned transaction that occurred on August 1, 2019, on the same day as and following Myriad's announcement that UnitedHealthcare had decided to cover the GeneSight test.[247] After the UnitedHealthcare announcement, Myriad stock price increased by 55% and the stock sales netted Capone and Riggsbee approximately $6 million and $1 million, respectively.[248]

Although pre-planned, Plaintiffs argue that the sales were highly suspicious when viewed in the context of surrounding events.[249] Neither Capone nor Riggsbee sold any shares during the eighteen months preceding the eighteen-month class period.[250] Then, just after Myriad announced extremely positive news, they sold approximately 23% and 10% of their shares, respectively,[251] all while knowing and not disclosing negative news, namely, that Myriad earlier withdrew its GeneSight ADHD and analgesic panels[252] and that the FDA had requested "commercially devastating" changes to the GeneSight test.[253] On August 13, 2019, twelve days after the pre-planned sales, Myriad then announced its earlier decision to withdraw the ADHD and analgesic panels[254] and announced that the FDA requested changes to the GeneSight test.[255] Myriad's stock dropped by 42%.[256]

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[247] ECF No. 34 at ¶¶ 25, 137, 217, 226; *see* ECF No. 57 at 52.

[248] ECF No. 34 at ¶ 209.

[249] *Id.*

[250] *Id.* at ¶¶ 208, 209.

[251] *Id.*

[252] *Id.* at ¶¶ 6, 23, 175.

[253] *Id.* at ¶ 129.

[254] *Id.* at ¶ 175.

[255] *Id.* at ¶ 177.

[256] *See id.* at ¶¶ 26, 27, 183.

Defendants respond that the pre-planned stock sales do not support an inference of scienter because they are not suspicious, citing cases that involved much larger stock sales, greater gains, and evidence that the pre-planned sales were subterfuge.[257] While some of those cases involved more egregious circumstances, they shed little light on whether the factual allegations in this case are sufficiently suspicious to create an inference of scienter. While Plaintiffs' allegations may or may not prove to be correct, taken together, their allegations may somewhat bolster scienter: Capone and Riggsbee sold large amounts of stock, resulting in significant profits, on the same day excellent insurance coverage news was announced, all while knowing that other material bad news (the withdrawal of the ADHD and analgesic panels and the significant prospect of "commercially devastating" changes to GeneSight at FDA's request) existed but would not be announced until two weeks later.

f. Intense Regulatory Scrutiny

Plaintiffs allege that regulatory scrutiny involving GeneSight supports an inference of scienter.[258] In October 2018, FDA issued a Safety Communication titled, "The FDA Warns Against the Use of Many Genetic Tests with Unapproved Claims to Predict Patient Response to Specific Medications."[259] Generally, the FDA expressed caution against "[g]enetic laboratory tests with claims to predict a patient's response to specific medications, that have not been reviewed by the FDA and may not be supported by clinical evidence."[260] The Safety Communication did not name any specific product or company.

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[257] ECF No. 67 at 17–18.

[258] *Id.*

[259] ECF No. 34 at ¶ 156.

[260] *Id.* at ¶¶ 157, 216.

Following the warning, Myriad sought to distinguish its product from those the FDA warned against. On November 6, 2018, Capone stated that the FDA was:

> well aware that there's a pretty significant difference between GeneSight, which is a combinatorial pharmacogenomic test that has clear clinical evidence demonstrating improved patient outcomes, [and] that that difference is pretty stark when you compare it to the single gene approach that one might see in the more recreational genomic testing.[261]

Plaintiffs allege that by May 2019 the FDA expressed concerns about the efficacy of the GeneSight test, and Myriad discontinued its ADHD and analgesic GeneSight panels because the available data did not support its claimed effectiveness.[262] Citing a third-party web posting on CaféPharma.com and a letter from the American Clinical Laboratory Association, Plaintiffs allege that the FDA demanded that Myriad stop offering pharmacogenomic tests that reference specific drugs or drug classes, or seek approval by the FDA.[263]

Defendants argue that the alleged "scrutiny" does not support scienter because the FDA Safety Communication makes no specific reference to GeneSight or Myriad and that for "almost a year from the date of such alleged FDA 'scrutiny,' there has been no action by the FDA and no mention by the FDA of scrutiny or oversight of Myriad or the GeneSight test."[264]

While Defendants identify relevant countervailing considerations, the regulatory scrutiny allegations here are at least as consistent with scienter, at least for statements after May 2019, as an innocent explanation. In isolation, the inference is not strong. However, in the broader context of alleged internal concerns expressed by Myriad scientists and a peer review panel at the

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[261] *Id.* at ¶ 163.

[262] *Id.* at ¶¶ 129, 175.

[263] *Id.* at ¶¶ 130, 131, 132.

[264] ECF No. 67 at 16–17.

American Journal of Psychiatry, the FDA scrutiny lends at least some support to the inference of scienter.

g. Executive Resignations and One Demotion

Plaintiffs allege that three executive departures and demotion of a fourth bolsters an inference of scienter. In July 2019, Myriad's General Counsel retired; in October 2019, Myriad's Chief Medical Officer resigned; on February 6, 2020 Myriad announced that Capone would resign "effective immediately;" and on February 10, 2020, Dechairo allegedly was demoted from his position as an executive officer.[265] Personnel changes may support an inference of scienter, although the plaintiff must "allege[] that the resignations were 'numerous,' 'uncharacteristic' in relation to the company's 'typical hiring and termination patterns' or were accompanied by 'suspicious circumstances.'"[266]

Plaintiffs allege that these personnel changes were suspicious primarily because of their timing: the General Counsel retired "while the FDA was expressing serious concerns about Genesight;" the Chief Medical Officer resigned "shortly after Myriad announced the withdrawal of GeneSight's ADHD and analgesic panels;" Capone resigned following "his highly suspicious sale of Myriad stock on August 1, 2019;" and Dechairo was demoted "closely on the heels of Myriad's shocking disclosures about GeneSight's efficacy."[267]

The court finds that these changes generally do little to bolster the scienter inference. The allegation regarding the General Counsel's retirement lends no support. The Chief Medical

[265] ECF No. 57 at 56; ECF No. 34 at ¶¶ 217–19.

[266] *Rumbaugh v. USANA Health Scis., Inc.*, 2018 WL 5044240, at *9 (D. Utah Oct. 17, 2018) (quoting *Zucco*, 552 F.3d at 1002 ("Although resignations, terminations, and other allegations of corporate reshuffling may in some circumstances be indicative of scienter, the resignations at issue here are not so numerous or suspicious as to raise such an inference."), *as amended* (Feb. 10, 2009)).

[267] ECF No. 34 at ¶¶ 217–19.

Officer's resignation came two months after the ADHD and analgesic panel withdrawal announcement, but the actual withdrawals occurred in May, six months before the resignation.[268] However, the Capone resignation and Dechairo demotion lend very modest scienter support because they occurred only days apart and because Capone's resignation was unusual in that it was effective immediately with no successor identified.[269]

h. The Allegations as a Whole

The strength of an inference of scienter "cannot be decided in a vacuum."[270] Indeed, the inquiry "is whether all of the facts alleged, taken collectively, give rise to a strong inference of scienter, not whether any individual allegation, scrutinized in isolation, meets that standard."[271] To allege scienter for pleadings purposes, Plaintiffs must plead facts showing that Defendants acted with a reckless disregard of a substantial likelihood of misleading investors."[272] "A complaint will survive . . . only if a reasonable person would deem the inference of scienter cogent and at least as compelling as any opposing inference one could draw from the facts alleged."[273]

Accordingly, the court briefly summarizes those allegations that, taken together, support scienter. Plaintiffs allege that Myriad knew that it did not have sufficient data to support the use of its ADHD and analgesic panels, but made numerous statements touting the efficacy of those

[268] *See id.* at ¶ 175 (alleging that Myriad announced its May 2019 withdrawal of the ADHD and analgesic panels on an August 2019 earnings call); *id.* at ¶ 219 ("Myriad's Chief Medical Officer . . . suddenly left Myriad in October 2019.").

[269] *See id.* at ¶¶ 217–19.

[270] *Tellabs*, 551 U.S. at 323.

[271] *Id.* at 322–23.

[272] *Nakkhumpun*, 782 F.3d at 1150.

[273] *Tellabs*, 551 U.S. at 324.

panels anyway.[274] Two or more medical science liaisons raised the lack of data with Dechairo and Veratti on multiple occasions.[275] Both refused to conduct needed testing.[276] When Myriad eventually withdrew the ADHD and analgesic panels, it prepared a script for use by its personnel with doctors asking them if they "want to prescribe a test to a patient that has little or no data?"[277]

Plaintiffs also allege that the heralded GUIDED study had no statistically significant results.[278] A statistical adjustment for the GUIDED remission and response secondary endpoints was needed to correct for multiplicity, and Myriad personnel knew the correction was needed, but Myriad did not perform the required adjustment.[279] Plaintiffs also allege that FDA guidance stated that no secondary endpoint analysis should be performed at all when the primary endpoint is not met, but that Myriad did so anyway, despite telling investors that GUIDED followed FDA guidance.[280]

Plaintiffs further allege that a panel of peer reviewers from the American Journal of Psychiatry twice warned Myriad privately that the GUIDED study data did not support the efficacy of GeneSight.[281] Capone also allegedly told investors in a November 2018 earnings call that Myriad had "voluntarily withdrawn" the GUIDED manuscript from publication review at

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[274] ECF No. 34 at ¶ 61.

[275] *Id.* at ¶¶ 62–66.

[276] *Id.* at ¶¶ 64, 65.

[277] *Id*. at ¶ 69.

[278] *See id.* at ¶¶ 16, 62, 65, 83.

[279] *Id.* at ¶ 200; *but see supra* note 141.

[280] ECF No. 34 at ¶ 200.

[281] *Id.* at ¶ 201.

the American Journal of Psychiatry "solely based upon the desire to protect our intellectual property," when in reality the manuscript had been rejected.[282]

Plaintiffs further allege that by May 2019, FDA expressed concerns to Myriad about the efficacy of the GeneSight test and that FDA demanded that Myriad stop offering pharmacogenomic tests that reference specific drugs or drug classes or seek approval by the FDA.[283]

Capone and Riggsbee later sold substantial amounts of Myriad stock in a pre-planned sale on August 1, 2019, on the same day as and following Myriad's announcement that UnitedHealthcare had decided to cover the GeneSight test.[284] After the UnitedHealthcare announcement, Myriad stock price increased by 55% and the stock sales netted Capone and Riggsbee approximately $6 million and $1 million, respectively.[285] On August 13, 2019, twelve days after the pre-planned sales, Myriad then announced its earlier decision to withdraw the ADHD and analgesic panels[286] and announced that the FDA requested changes to the GeneSight test.[287] The stock priced then dropped by 42%.[288]

Plaintiffs further allege that Myriad recklessly overstated revenue on its hereditary cancer tests.[289] The tests were under pricing pressure because of billing code changes from 2016 to

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[282] *Id.* at ¶¶ 123, 257.

[283] *Id.* at ¶¶ 130, 131, 132.

[284] *Id.* at ¶¶ 25, 137, 217, 226; *see* ECF No. 57 at 52.

[285] ECF No. 34 at ¶ 209.

[286] *Id.* at ¶ 175.

[287] *Id.* at ¶ 177.

[288] *Id.* at ¶ 27.

[289] *Id.* at ¶¶ 140, 141.

2019.[290] Despite the downward pressure on pricing, Myriad allegedly continued to report on its books the higher expected revenue[291] and did not comply with GAAP by failing to identify this contingency.[292] Myriad also made multiple statements in 2019 regarding its cancer panel pricing that did not reflect the pricing situation, including the phrases "stable hereditary cancer pricing" and "pricing headwinds abated."[293] By June 2019, Myriad had observed an increase in the number of denied claims and "short" payments for its hereditary cancer tests.[294] On November 4, 2019, Myriad disclosed that it had overstated the revenue for its cancer tests by $18 million.[295]

Finally, two prominent executives resigned or were demoted within days of each other.[296] Capone resigned "effective immediately" on February 6, 2020, despite the lack of a named successor, and Dechairo allegedly was demoted from his position as an executive officer four days later.[297]

Taken together, Plaintiffs have alleged facts sufficient to support a cogent and strong inference of scienter that is at least as compelling as the innocent alternative.[298] If the many facts

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[290] *Id.* at ¶¶ 143–45.

[291] *Id.* at ¶ 145.

[292] *Id.* at ¶¶ 298, 299.

[293] *Id.* at ¶ 303.

[294] *Id.* at ¶ 148.

[295] *Id.* at ¶ 141.

[296] *Id.* at ¶¶ 217–19.

[297] ECF No. 57 at 56; ECF No. 34 at ¶¶ 217–19.

[298] Some of the foregoing allegations considered independently are also consistent with negligence or gross negligence. Of course, negligence or gross negligence do not meet the scienter standard. *In re Zagg, Inc. Securities Litigation*, 797 F.3d 1194, 1206 (10th Cir. 2015). Considered as a whole, the allegations, if true, support the kind of recklessness that is "akin to conscious disregard." *Id.* at 207 (citation omitted).

alleged are true, a reasonable fact finder could find that the Defendants at least acted with a "reckless disregard of a substantial likelihood of misleading investors."[299]

B. Plaintiffs Have Adequately Pleaded Section 20(a) and Section 20A Claims Under the Exchange Act.

Section 20(a) of the Securities Exchange Act of 1934 imposes joint and several liability for controlling persons who aid in securities violations.[300] "[T]o state a prima facie case of control person liability, the plaintiff must establish (1) a primary violation of the securities laws and (2) 'control' over the primary violator by the alleged controlling person."[301] Defendants argue only that Plaintiffs have failed to plead a predicate violation under the Exchange Act.[302] As explained above, however, the Amended Complaint adequately alleges a Section 10(b) claim.

C. Plaintiffs Have Adequately Pleaded Section 20A Claims Under the Exchange Act.

Section 20A of the Securities Exchange Act authorizes damages against "[a]ny person who violates any provision of this chapter or the rules or regulations thereunder by purchasing or selling a security while in possession of material, nonpublic information."[303] To meet the statutory requirements, the complainant must have, "contemporaneously with the purchase or sale of securities that is the subject of such violation, . . . purchased (where such violation is based on a sale of securities) or sold (where such violation is based on a purchase of securities)

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[299] *Nakkhumpun*, 782 F.3d at 1150.

[300] 15 U.S.C. § 78t(a) ("Every person who, directly or indirectly, controls any person liable under any provision of this chapter or of any rule or regulation thereunder shall also be liable jointly and severally with and to the same extent as such controlled person to any person to whom such controlled person is liable (including to the Commission in any action brought under paragraph (1) or (3) of section 78u(d) of this title), unless the controlling person acted in good faith and did not directly or indirectly induce the act or acts constituting the violation or cause of action.").

[301] *City of Philadelphia*, 264 F.3d at 1270 (citation and internal quotation marks omitted).

[302] ECF No. 51 at 47–48.

[303] 15 U.S.C. § 78t-1(a).

securities of the same class."[304] Additionally, "[c]ourts have interpreted § 20A as requiring the plaintiff to plead a predicate violation of the 1934 Act or its rules and regulations," such as a Section 10(b) claim.[305] As addressed above, Plaintiffs have alleged a predicate violation of the Exchange Act, so that requirement is met.

Defendants also contend that the Plaintiffs lack standing because they did not make a contemporaneous trade as required by the statute. Section 20A does not identify the scope of the term "contemporaneous" but the court concludes that it may include a two-day gap in trades.[306] Plaintiffs allege that Lead Plaintiff Los Angeles purchased Myriad common stock on July 13, 2018, two days after Defendant Capone sold stock.[307] Plaintiffs also allege the sales occurred while Capone was in possession of material, nonpublic information concerning the efficacy of the GeneSight ADHD and analgesic panels and concerns about the GUIDED study data.[308] Plaintiffs' purchase occurred shortly after Defendants' sale and while Defendants allegedly withheld negative information about Myriad's key products.[309] These transactions were sufficiently contemporaneous to support standing under Section 20A.[310]

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[304] *Id.*

[305] *Sterlin v. Biomune Sys.*, 154 F.3d 1191, 1194 n.5 (10th Cir. 1998).

[306] *See In re Qwest Commc'ns Int'l, Inc.*, 396 F. Supp. 2d 1178, 1201 (D. Colo. 2004) (observing that "various courts have read [the contemporaneous trade] requirement to encompass trades on the same day, within the same week, within a month, and including 'the entire period while relevant and nonpublic information remained undisclosed'" (quoting *In re Enron Corp. Sec., Derivative & ERISA Litig.*, 258 F. Supp. 2d 576, 599–600 (S.D. Tex. 2003)).

[307] ECF No. 34 at ¶ 333.

[308] *Id.*

[309] *Id.*

[310] *Cf. In re Overstock Sec. Litig.*, 2020 WL 5775845, at *14, Slip Copy, (D. Utah Sept. 28, 2020) (finding no contemporaneous trade where Defendant's "stock sales occurred three to five calendar days *after* Plaintiff purchased Overstock shares and after the alleged short squeeze was over" (emphasis added)).

Lastly, Defendants suggest that the court should consider the information held by Defendants at the time they decided to sell stock, rather than the information known at the time of the trade.[311] However, the plain language of the Exchange Act requires a showing that the trades were contemporaneous while the defendant was "in possession of material, nonpublic information."[312] Here, Plaintiffs have adequately alleged that, at the time of the stock sales, Capone and Riggsbee knew that GeneSight panels' efficacy had not been validated. Accordingly, Plaintiffs have standing to assert a claim under Section 20A of the Exchange Act.

ORDER

For the reasons stated in this Memorandum Decision and Order, the court DENIES Defendants' Motion to Dismiss.[313] Plaintiffs' Motion to Strike is GRANTED and Plaintiffs' Request for Judicial Notice is DENIED.

Signed March 16, 2021.

BY THE COURT

David Barlow
United States District Judge

[311] ECF No. 51 at 48.

[312] 15 U.S.C. § 78t-1(a).

[313] ECF No. 51.